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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,072

Applicant(s)

DINMAN ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-18 are pending in the present application. Claims 1-16 are withdrawn from consideration. Claims 17 and 18 are currently under examination.

Election/Restrictions

Applicant's election without traverse of Group 3 in the reply filed on 28 July 2005 is acknowledged. Claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 28 July 2005. Accordingly, claims 17 and 18 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to

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consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) The quantity of experimentation necessary,
- 2) The amount of direction or guidance provided,
- 3) The presence of absence of working examples,
- 4) The nature of the invention,
- 5) The state of the prior art,
- 6) The relative skill of those in the art
- 7) The predictability of the art, and
- 8) The breadth of the claims.

Nature and of the invention and the breadth of the claims.

The invention of the instant claims is very broadly drawn to a method of treating disease by increasing the frequency of ribosomal frameshift during translation. The nature of the invention involves the treatment of any disease by modulating the translation machinery of a cell.

State and predictability of the art.

Ribosomal frame shift allows for the translation of different proteins using the same mRNA by shifting the reading frame of the mRNA. Shifting the reading frame of the mRNA allows the ribosome to begin translation at different codons. The method of the instant claims comprising increasing ribosomal frameshifting during translation. It is not apparent from the art

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which diseases could be treated by increasing frameshifting and whether disease can be treated at all based on frameshifting. Smania et al. analyze phenotypic variants of mutS, which is a gene in the bacterial mismatch repair system. Smania et al. state that phenotypic diversity in mutS is produced in part by frameshift mutations. If frameshift frequency is increased as claimed in the present method, the disclosure of Smania suggests to one of skill in the art that increase in frameshift frequency would result in increased mutation of the protein being translated by the ribosome. See Smania, page 1327. It is unpredictable how increased mutations in a translated protein could result in the treatment of disease. Moreover, how could one of skill in the art extrapolate such results into treatment of the breadth of disease embraced by the claims.

The amount of guidance and presence of working examples.

The specification fails to enable one of skill in the art to make and use the invention claimed. The specification teaches methods for determining consensus -1 ribosomal frameshift signals. See pages 4-6. The specification also teaches three human genes where mutation in the consensus -1 ribosomal frameshifting signals have been linked to disease. See page 10. The specification also discloses that there are "possible regulatory roles of programmed -1 ribosomal frameshifting." Although the specification discloses that -1 ribosomal frameshifting is linked to disease and that there are possible regulatory roles of programmed -1 ribosomal frameshifting, it fails to provide guidance or working examples as to how diseases may be treated by increasing ribosomal frameshifting. The specification also fails to provide guidance or working examples providing a nexus between a disease state and ribosomal frameshift such that one of skill in the

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art would be able to increase ribosomal frameshift to treat disease without undue experimentation.

In summary, the unpredictability of the art, the lack of working examples in the specification, the lack of guidance of the specification, and the breadth of the invention would not allow one of skill in the art to make and use the invention claimed without undue experimentation.

Claims 17 and 18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

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The instant claims are drawn to undefined gene products expression of which is reduced as a result of ribosomal frameshifting. This a broad genus for which Applicant does not provide adequate description so that one of skill in the art would reasonably concluded that Applicant had possession of all gene products embraced by these claims. The specification does not disclose a representative number of species or common structure of these gene products that relate to function to describe the invention consistent with the statute. Absent teachings and guidance as to the structure-function relationship of the genus of gene products or teachings of a representative number of species of gene products, the specification does not describe the claimed genus molecules in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these molecules at the time of filing of the present application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted method step involves an active method step which provides a nexus between an active step and increase in frequency in ribosomal frameshifting. Claims 17 and 18 only a single functional method step.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636


JAMES KETTER
PRIMARY EXAMINER